General

Guideline Title

Clinical practice guideline for the treatment of patients with axial spondyloarthritis and psoriatic arthritis.

Bibliographic Source(s)

Spanish Society of Rheumatology (SER). Clinical practice guideline for the treatment of patients with axial spondyloarthritis and psoriatic arthritis. Madrid (Spain): Spanish Society of Rheumatology (SER); 2015. 120 p. [222 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Espoguia Group. Espoguia. Clinical guidelines for patients with spondyloarthritis. Madrid: Spanish Society of Rheumatology; 2010. 289 p. [1104 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the grades of recommendations (A-D) are provided at the end of "Major Recommendations" field and, in more details, in Appendix 1 of the original guideline document.

Treatment of Axial Spondyloarthritis (axSpA)

- In patients with active axial spondyloarthritis (axSpA), it is recommended that pharmacological treatment begin as soon as possible. (Grade D recommendation)
- Therapy with anti-tumour necrosis factor (TNF) is recommended as the pharmacological treatment of choice for patients with active* non-radiologic axial spondyloarthritis who are refractory to non-steroidal anti-inflammatory drugs (NSAIDs). (Grade A Recommendation)
  *Defined by objective inflammation characteristics (increase in C-reactive protein [CRP] and/or magnetic resonance imaging [MRI]).
- The use of tocilizumab is not recommended in patients with non-radiographic axial spondyloarthritis who are refractory to NSAID and/or treatment with anti-TNF. (Grade C Recommendation)
- In those patients with axial spondyloarthritis who reach the clinical objective, halting anti-TNF therapy is not recommended. (Grade C recommendation).
- In those patients with ankylosing spondylitis who reach the clinical objective following administration of standard dosage anti-TNF, the possibility of reducing the dosage should be assessed. (Grade C recommendation)
- The guideline development group believes that in patients with ankylosing spondylitis, the use of anti-TNF, especially monoclonal antibodies,

is effective in reducing the number of uveitis recurrences and improving visual prognosis. However, its superiority (or inferiority) in comparison with sulfasalazine cannot be established based on current scientific evidence. (Grade D recommendation)
- It is recommended that adults with ankylosing spondylitis exercise, preferably in supervised groups, as part of their disease treatment, to improve symptoms, quality of life, and health-related fitness. (Grade B recommendation)
- The previous recommendation is extended to patients with non-radiographic axial spondyloarthritis. (Grade D recommendation)
- Exercise programs must include aerobic exercises, preferably performed in supervised groups. (Grade B recommendation)
- It is recommended that patients with axial spondyloarthritis be encouraged to stop smoking from the time of diagnosis. (Grade C recommendation)

Treatment of Psoriatic Arthritis (PsA)

- In patients with active peripheral psoriatic arthritis, it is recommended that pharmacologic treatment start as soon as possible. (Grade D recommendation)
- Biologic monotherapies have proven more effective than disease-modifying antirheumatic drugs (DMARDs) or a placebo in treating patients with psoriatic arthritis in its different manifestations: peripheral, axial, enthesitis, dactylitis, and uveitis. (Grade D Recommendation)
- Traditional DMARDs (methotrexate, leflunomide, sulfasalazine) are recommended as first line treatment for active peripheral psoriatic arthritis (Grade C recommendation)
- Among them, methotrexate is considered first choice treatment due to its effects on arthritis and psoriasis (Grade D recommendation)
- These drugs should not be used to treat symptoms of axial disease. There is no evidence supporting their use against enthesitis. There are questions about their effectiveness against dactylitis. (Grade C recommendation)
- The use of biologic therapy, either in monotherapy or when combined with methotrexate, for PsA patients refractory to DMARD is recommended. Combined therapy with methotrexate may increase the survival rate of anti-TNF drugs, especially monoclonal antibodies. (Grade C recommendation)
- It is recommended that dermatologists and rheumatologists work closely together in order to gain optimal control over the psoriatic disease. (Grade D recommendation)
- This type of consultation is recommended whenever a multidisciplinary approach can be arranged at the health center of reference. (Grade D recommendation)

Treatment of Axial Spondyloarthritis (axSpA) and Psoriatic Arthritis (PsA)

- Participation of clinical nurse specialists is recommended, either in person or by telephone, in follow-up consultations for patients with axial spondyloarthritis or with psoriatic arthritis due to evidence it increases patient satisfaction. (Grade D recommendation)
- Patients who are smokers and suffer from axial spondyloarthritis or psoriatic arthritis could benefit from implementation of educational tobacco cessation programs provided by a nurse, since evidence show they increase smoking quit rates. (Grade D recommendation)
- Nurse-run educational workshops prior to the start of subcutaneous therapy are recommended since they help lower patient fear of this treatment type. (Grade D recommendation)
- The assistance of a nurse to clarify any doubts and help patients complete self-assessment questionnaires is recommended, provided that the patient opinions and preferences are not influenced. (Grade D recommendation)
- Patients with psoriatic arthritis could benefit from educational programs, preferably in a group setting led by a clinical nurse specialist. This would facilitate patient self-management and treatment adherence (Grade D recommendation)

General Advice for Patient Management

- The management of patients with axial spondyloarthritis or psoriatic arthritis must be carried out by taking into account each patient's individual characteristics. (Grade D recommendation)
- Before early implementation of treatment for axial spondyloarthritis or psoriatic arthritis, patients must be properly informed regarding pharmacological properties and side effects, treatment duration, expected benefits and possible secondary effects, taking their preferences into consideration. (Grade D recommendation)
- In prescribing biologics particular attention must be paid to the patient's age, preferences, tolerance, previous treatment, secondary effects, possibility of pregnancy, and cost benefits. (Grade D recommendation)
- The patient and/or family should be instructed regarding self-care of joints, and self-management of biologic therapy. (Grade D recommendation)
- Health care professionals will offer information to patients with axial spondyloarthritis regarding the most appropriate physical exercise. (Grade D recommendation)
- The health care professional will give patients with axial spondyloarthritis information regarding tobacco cessation programs. (Grade D recommendation)

Definitions

Grades of Recommendation

A - Consistent level 1 studies

B - Consistent level 2 or 3 studies or extrapolations* from level 1 studies

C - Level 4 studies *or* extrapolations* from level 2 or 3 studies

D - Level 5 evidence *or* troublingly inconsistent or inconclusive studies of any level

*"Extrapolations" are used in a situation that has potentially clinically important differences from the original study situation.

See also the table in Appendix 1 of the original guideline document, "Levels of Evidence and Recommendations," from Oxford Centre for Evidence-Based Medicine.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Axial spondyloarthritis (axSpA)
- Psoriatic arthritis (PsA)

Guideline Category

Counseling

Management

Rehabilitation

Treatment

Clinical Specialty

Dermatology

Family Practice

Internal Medicine

Nursing

Physical Medicine and Rehabilitation

Rheumatology

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

Primary Objective

To provide guidance to rheumatologists on treatment recommendations based on the available scientific evidence, specifically, therapeutic interventions for the management of adult patients suffering from axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA)

Specific Objectives

- To increase the skills of health professionals involved in caring for patients with axSpA and PsA in order to improve the quality of care offered
- To reduce variability in clinical practice in the therapeutic management of these pathologies
- To assess the effectiveness, safety, and efficiency of the different pharmacological and non-pharmacological approaches available
- To summarize the scientific evidence in order to increase the knowledge of all professionals involved in the care process
- To establish recommendations to standardize the care of patients with axSpA and PsA
- To encourage collaboration between professionals from various specialties who are involved in patient management. In the specific case of PsA, collaboration between dermatology and rheumatology is considered essential for the satisfactory management of such patients.
- To develop general information material for the population affected by axSpA or PsA, as well as their relatives and caregivers, to allow a better understanding of the process and aspects affecting disease progression

Target Population

Adult patients (≥18 years) with axial spondyloarthritis (axSpA) and/or psoriatic arthritis (PsA)

Interventions and Practices Considered

1. Pharmacological treatment
    - Anti-tumour necrosis factor (TNF) agents, including monoclonal antibodies
    - Biological monotherapies
    - Traditional disease-modifying antirheumatic drugs (DMARDS), including methotrexate, leflunomide, and sulfasalazine
2. Non-pharmacological treatment
    - Advice regarding exercise
    - Smoking cessation
    - Information for patients regarding pharmacological properties and side effects, treatment duration, and expected benefits and possible secondary effects
    - Nurse-run educational workshops prior to start of subcutaneous therapy
    - Education programs, preferably in a group setting
    - Follow-up consultations with a nurse
    - Instructions to patient and/or family regarding self-care of joints and self-management of biologic therapy

Major Outcomes Considered

- Incidence and prevalence of spondyloarthritis (SpA) and psoriatic arthritis
- Disease signs and symptoms (axial and peripheral)
- Disease activity score
- Number of painful and swollen joints

- Rate of disease progression
- Radiologic structural damage
- Functional status
- Quality of life/patient satisfaction

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

A literature search was carried out using the MEDLINE database (via PubMed), EMBASE (Elsevier), the Cochrane Library (Wiley Online Library), and CINAHL (EBSCOhost). The question regarding physiotherapy was researched in PEDro (Physiotherapy Evidence Database). These databases were selected because they are not only readily accessible, but also constitute some of the main resources for biomedical information today.

Literature and database searches were limited to those studies published after the creation of ESPOGUIA 2009, i.e., from the beginning of 2008. These searches were completed at the end of 2014. Initially, all search strategies sought only to recover the primary studies in the aforementioned databases. However, if the results proved to be poor or inconsequential, then a supplemental search by hand among the bibliography in the most relevant documents was conducted. Further material was included after consulting with investigators and reviewers. This helped identify those studies published since the initial search until the current guideline was created, 2015. The studies examined included publications in Spanish, English, and French.

EndNote X7 was used to manage the relevant references. The search strategy for the different databases is detailed in full in Spanish in the methodology supplement (see the "Availability of Companion Documents" field).

In total, 8,388 references were identified. Each title and abstract was reviewed in order to select those references that could best answer a given clinical question. A total of 431 were selected for a full review; among these, 84 original articles and reviews met the inclusion criteria.

Studies Inclusion Criteria

The included studies had the following characteristics:

Study Population

Adults diagnosed with axial spondyloarthritis (axSpA), non-radiographic axial spondyloarthritis (nr-axSpA), ankylosing spondylitis (AS), or psoriatic arthritis (PsA)

Intervention

Early treatment, disease-modifying antirheumatic drugs (DMARDs), biologic therapy (BT), multidisciplinary dermatology-rheumatology management of patients, health education programs, treatment discontinuation, rehabilitative intervention, smoking habits

Outcome Variables

Efficacy in dealing with the disease cutaneous and musculoskeletal activity measured by the usual clinical parameters; axial and peripheral symptoms, enthesopathy by sonography or magnetic resonance imaging (MRI), dactylitis, uveitis, visual prognosis, radiologic structural damage, functional capacity, quality of life

Studies Design

Systematic reviews (SR) of randomized clinical trials (RCT), RCT phase III or IV double blind, and observational studies that lasted a minimum of ≥6 months in ≥50 patients.

Exclusion Criteria

The following studies were not included in this clinical practice guideline (CPG): 1) studies including children, adolescents, and pregnant women; 2) studies that did not adjust for Patient-Intervention-Comparison-Outcome (PICO) methodology variables related to patient sample size, intervention, comparisons, outcomes, or study design; and 3) abstracts, posters, narrative reviews, letters, editorials, and any studies that had not been published.

Number of Source Documents

A total of 84 original articles and reviews met the inclusion criteria.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

See Table in Appendix 1 of the original guideline document.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Quality Assessment of Studies

Studies were selected based on the inclusion and exclusion criteria specified in the "Description of Methods Used to Collect/Select the Evidence" field. A critical reading of the studies was conducted using the critical Scottish Intercollegiate Guidelines Network (SIGN) reading templates, and their internal and external validity measures were assessed. From the selected studies, the most significant data referring to methodology, outcomes, and quality (see the methodology supplement [see the "Availability of Companion Documents" field]) were extracted and entered in evidence tables. The level of scientific evidence was evaluated using a modified version of the Oxford Centre for Evidence-Based Medicine (CEBM) system (http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development Group

A multi-disciplinary work group was set up consisting of professionals involved in medical care, technical experts from the Research Unit (RU) of the Spanish Society of Rheumatology (SER), and patient representatives. The composition of the group is described below.

- *Coordination*: A rheumatology specialist serving as the principal investigator (PI), and a methodology specialist, who is also a technical

expert from the RU of SER, were charged with coordinating all clinical and methodological aspects of the clinical practice guideline (CPG), as well as supporting the guideline development group.
- *Experts Group*: Rheumatology, dermatology, specialized nursing, rehabilitation, and ophthalmology specialists were selected through a public appeal via the participating scientific societies. As members of an expert panel, they supervised the drafting of recommendations for the CPG.
- *Reviewers*: Various reviewers from SER were responsible for systematically reviewing the available scientific evidence.
- *Patients*: Apart from health professionals, two patients also participated in the working group from its early stages.

A project calendar was set up establishing different phases and deadlines.

Scope and of Objectives

Updating the former Espoguía was deemed necessary due to the time elapsed since its last publication and because of new findings and advances. The former guideline has been partially updated and is hereby replaced with the new clinical practice guideline (CPG). Delimitation in the scope and objectives of the CPG was consensually determined, drawing upon the clinical experience and information provided by the participating health professionals.

Formulating Clinical Questions

After defining the CPG's scope and objectives, the members of the guideline development group formulated the key clinical questions that had to be answered. A list of generic clinical questions was also created. Those questions that addressed the guideline objectives were selected and rephrased using the Patient-Intervention-Comparison-Outcome (PICO) method (see section 5 of the original guideline document).

Formulation of Recommendations

After the considered review, recommendations were formulated. These formulations were based on the 'formal evaluation' or 'reasoned judgement' after previously summarizing the best available evidence for each clinical question. The strength of each recommendation was evaluated using a modified version of Oxford Centre for Evidence-Based Medicine (CEBM) (http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/) Recommendations that proved controversial or that lacked sufficient evidence were submitted to the development group consensus.

Rating Scheme for the Strength of the Recommendations

The Oxford Centre of Evidence-Based Medicine classification scheme was used. This classification allows calculating the strength of the recommendations and evaluating the quality of evidence based on the best design to answer the question (see Table in Appendix 1 of the original guideline document).

Grades of Recommendation

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C - Level 4 studies *or* extrapolations* from level 2 or 3 studies

D - Level 5 evidence *or* troublingly inconsistent or inconclusive studies of any level

*"Extrapolations" are where data is used in a situation that has potentially clinically important differences from the original study situation.

Cost Analysis

- The guideline development group concluded that obtaining a good clinical response, even clinical remission, could ultimately minimize direct and indirect care costs.
- The studies show the powerful anti-inflammatory properties of anti-tumour necrosis factor (TNF) therapy in patients with non-radiographic axial spondyloarthritis (nr-axSpA). Since the population is young and of working age, this will result in social and healthcare cost savings.
- Disease-modifying antirheumatic drugs (DMARDs) have emerged as a cost-effective and safe alternative for the initial treatment of psoriatic arthritis (PsA), mainly in its peripheral forms.
- In formulating the recommendation, the guideline development group believes that, in terms of cost optimization, multidisciplinary

consultations (dermatology-rheumatology) would translate to a decrease in the overall frequency of consultations.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Guideline External Review and Final Document Edition

An advanced draft of the clinical practice guideline (CPG) was developed, and the work group reviewed it. Each section was analyzed, and any necessary amendments were considered for inclusion.

Subsequently an external revision was carried out by professionals selected based on their expertise in the relevant pathology and in the creation of clinical guidelines.

Scientific societies involved in this guideline development, which are represented by members of the work group are as follows: the Association of Psoriasis and Psoriatic Arthritis Patients and Families; the Spanish Society of Rheumatology (Spanish acronym, SER); the Spanish Academy of Dermatology and Venerology (Spanish acronym, AEDV); the Spanish Society of Ophthalmology (Spanish acronym, SEO); the Spanish Society of Rehabilitation and Physical Medicine (Spanish acronym, SERMEF); and the Spanish League Against Rheumatism (Spanish acronym, LIRE).

Public Display

The draft CPG was subject to public comment by SER associate members and different interest groups (the pharmaceutical industry, other scientific societies, and patient associations). It was available for a 21-day period, at the SER website, together with a submission form that sought to collect scientific input on the methodology and recommendations put forth by the CPG.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate management of patients with axial spondyloarthritis and psoriatic arthritis
- Increased patient satisfaction
- Multidisciplinary consultations (dermatology-rheumatology) would translate to a decrease in the overall frequency of consultations. Moreover, patients' perception of quality and comfort seems to improve, while the duplication of visits and tests is reduced. The ability to detect de novo psoriatic arthritis also seems to increase, making it possible to treat the disease from its earliest stages, and to improve diagnosis. However, further well-designed studies with larger patient samples, and under long-term disease conditions, are needed to confirm these potential benefits.

Potential Harms

Adverse effects of disease-modifying antirheumatic drugs (DMARDs) and biologic treatment (BT)

Qualifying Statements

Qualifying Statements

This Clinical Practice Guideline is meant to help in healthcare decision-making. It is not mandatory and does not replace professional clinical judgement.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Foreign Language Translations

Patient Resources

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Spanish Society of Rheumatology (SER). Clinical practice guideline for the treatment of patients with axial spondyloarthritis and psoriatic arthritis. Madrid (Spain): Spanish Society of Rheumatology (SER); 2015. 120 p. [222 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015

Guideline Developer(s)

Spanish Society of Rheumatology - Medical Specialty Society

Source(s) of Funding

This clinical practice guideline (GPC), sponsored by the Spanish Society of Rheumatology (SER), was financed by AbbVie. The Spanish Foundation of Rheumatology (Spanish acronym, FER), which as the only intermediary employs the SER Research Unit staff and coordinates payments to panelists and reviewers, signed this contract with the pharmaceutical company. This agreement established total independence from the pharmaceutical company, which could not influence the panelist selection, the gathering and interpretation of evidence, or any other aspects of the final version of the CPG. The pharmaceutical company also committed to finance the CPG, even if the evidence contradicted any of its products' indications. Thus, the design, analysis, and interpretation of results have been carried out in a strictly independently fashion from AbbVie.

Guideline Committee

The ESPOGUIA Development Group for the Treatment of Axial Spondyloarthritis and Psoriatic Arthritis

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Financial Disclosures/Conflicts of Interest

See Appendix 3, "Declaration of Interests," in the original guideline document.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Espoguia Group. Espoguia. Clinical guidelines for patients with spondyloarthritis. Madrid: Spanish Society of Rheumatology; 2010. 289 p. [1104 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available in English and Spanish from the Spanish Society of Rheumatology Web site.

Availability of Companion Documents

The following are available:

- Quick reference guide. Madrid: Spanish Society of Rheumatology; 2015. 13 p. Available in Spanish from the Spanish Society of Rheumatology Web site.
- Methodology supplement. Madrid: Spanish Society of Rheumatology; 2015. 200 p. Available in Spanish from the Spanish Society of Rheumatology Web site.
- Public display supplement. Madrid: Spanish Society of Rheumatology; 2015. 12 p. Available in Spanish from the Spanish Society of Rheumatology Web site.

Patient Resources

The following are available:

- Learn to live with ankylosing spondylitis. Madrid: Spanish Society of Rheumatology; 2016 Jan. 48 p. Available in Spanish from the Spanish Society of Rheumatology Web site.
- Learn to live with psoriatic arthritis. Madrid: Spanish Society of Rheumatology; 2016 Jan. 34 p. Available in Spanish from the Spanish Society of Rheumatology Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on October 24, 2011. The information was verified by the guideline developer on November 2, 2011. This summary was updated by ECRI Institute on October 28, 2013 following the U.S. Food and Drug Administration advisory on Acetaminophen. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on September 28, 2016. The updated information was verified on October 10, 2016.

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